

Remarks/Arguments:

I. Status

The Office Action dated January 29, 2007 (the "Office Action"), has been carefully reviewed. Claims 1, 3, 8, 9, and 12 have been amended, claims 4-7 have been deleted and claims 14-18 have been added. Accordingly, claims 1-3 and 8-18 are pending in this application. Reconsideration of this application is respectfully requested.

II. 35 U.S.C. § 103 Rejections.

Claims 1-3, 8 and 12-13 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent Publication No. 62003/0069644 to Kovacevic et al. (hereinafter "Kovacevic"). Reconsideration of these claims in view of the following remarks is respectfully requested.

Discussion Re: Patentability of Claim 1

1. Claim 1

Claim 1 recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member;

a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cavities opening away from said upper plate, each of said cavities including a diaphragm adapted to flex when subjected to a load normal to the diaphragm;

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cavities, wherein said support posts are circular in cross-section; and

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm.

Claim 1 thus recites a telemetric knee prosthesis which uses a plurality of support posts with circular cross-sections.

2. The Cross-Section of the Support Post is Significant

The Examiner has acknowledged that Kovacevic does not disclose the use of a circular cross-section. (Office Action at page 3). The Examiner argues, however, that the use of a circular post is nothing more than “a mere change in shape” of the component and as such, is “within the level of ordinary skill in the art.” Respectfully, the Examiner has misapplied the relevant case law.

Specifically, the Examiner cited to *In re Rose*, 105 USPQ 237 (CCPA 1955) for the proposition that mere changes in shape were not patentable. *Rose*, however, is not directed to differences in the shape of elements. Rather, as further attested to by MPEP 2144.04, *Rose* dealt with the “sizing-up” of dimensions. (See, e.g., *Rose* at 240). Thus, *Rose* does not provide support for the proposition that a difference in shape is an obvious design choice.

As recognized in the MPEP, there are situations wherein the change in shape of a component is not a patentable difference. The case identified in the MPEP for this proposition is *In re Dailey*, 149 USPQ 47 (CCPA 1966). *Dailey* notes, however, that the applicant in that case “presented no argument which convinces us that the particular configuration of their container is significant...” (*Dailey* at 50). In contrast to the situation in *Dailey*, the Applicants’ specification clearly identifies the importance of the shape of the support structures. For example, at page 7, lines 7-9 the Specification states

that the posts are “circular, which maximizes the load-bearing area of the posts without sacrificing flex responsiveness of the load diaphragm to which the posts are attached.” Thus, the shape is important not only for the ability of the device to support a load, but also in determining the operational characteristics of the load diaphragm.”

Therefore, in contrast to the situation in *Dailey*, the Applicants have explained why the cross-section of the support ports is a significant limitation. Accordingly, a rejection based upon *Dailey* is not supported and claim 1 is patentable over the prior art.

3. Conclusion

For the foregoing reasons, it is respectfully submitted that the rejection of claim 1 as being obvious over Kovacevic has been successfully traversed, and the Applicants respectfully submit that the rejection of claim 1 under 35 U.S.C. § 103 should be withdrawn.

Discussion Re: Patentability of Claims 2 -3

As an initial matter, claims 2-3 depend from claim 1 and include the limitations discussed above with respect to claim 1 and additional limitations. Accordingly, for at least the same reasons set forth above with respect to claim 1, claims 2-3 are patentable over the prior art.

Moreover, the Examiner has argued that claims 2 and 3 are obvious as only “discovering an optimum value of a result effective variable”. (Office Action at page 3). Respectfully, the cited case does not provide support for the Examiner’s argument. Specifically, the Examiner has relied upon *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Boesch, however, dealt with claims directed to ranges of constituents that overlapped ranges disclosed by the prior art. (*Boesch* at 218). In contrast, Kovacevic does not disclose any size for the posts disclosed therein. A size was disclosed in the Applicants' specification. Specifically, the prior art was identified as a rectangle with 2.5 mm sides (page 10, line 12) which corresponds to about 6.25 mm². In contrast, claim 2 recites a diameter of about 5.0 mm which the specification corresponds to about 20 mm². (See, e.g., Specification at page 11, line 20). Thus, the limitations set forth in the claims do not overlap a range disclosed in the prior art. Therefore, *Boesch* does not provide support for an obviousness rejection of claims 2 and 3.

Accordingly, for any of the above reasons, claims 2-3 are patentable over the prior art.

Discussion Re: Patentability of Claim 8

1. Claim 8

Claim 8 recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member;

a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cylindrical cavities opening away from said upper plate, each of said plurality of cylindrical cavities including a circular diaphragm adapted to flex when subjected to a load normal to the diaphragm and an outer wall;

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cylindrical cavities; and

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm, said force sensing element including four pairs of radially aligned strain gages, the strain gages of each pair arranged to measure differential strain in a radial direction and includes an inner gage mounted on said diaphragm adjacent the center of said circular diaphragm and an

outer gage mounted on said diaphragm immediately adjacent said outer wall of said cylindrical cavity, wherein said circular diaphragm exhibits a micro-strain behavior under load that produces a maximum magnitude at a radial location from the center of said circular diaphragm, and further wherein said inner gage is positioned to span said maximum magnitude radial location.

Claim 8 thus recites a telemetric knee prosthesis with an inner gage positioned to span a maximum magnitude radial location.

2. The Prior Art does Not Disclose Spanning a Maximum Magnitude Location

The Examiner did not specifically address the limitation of an inner gage positioned to span a maximum magnitude radial location. The Applicants believe that the intent was to include claim 8 in the listing of claims which included allowable subject matter since this limitation has not been identified in the prior art. In the event this is not correct, the Applicants respectfully request the Examiner to set forth the basis for the rejection of claim 8 with more particularity.

3. Conclusion

For the foregoing reason, it is respectfully submitted that the rejection of claim 8 as being obvious over Kovacevic has been successfully traversed, and the Applicants respectfully submit that the rejection of claim 8 under 35 U.S.C. § 103 should be withdrawn.

Discussion Re: Patentability of Claim 12

1. Claim 12

Claim 12, as amended, recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member;

a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cavities opening away from said upper plate, each of said plurality of cavities including a diaphragm adapted to flex when subjected to a load normal to the diaphragm, said lower plate further defining a central cavity disposed between said plurality of cavities and a plurality of wiring channels, each communicating between a corresponding one of said plurality of cavities and said central cavity;

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cavities;

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm said force sensing element including four pairs of radially aligned strain gages, the strain gages of each pair arranged to measure differential strain in a radial direction;

a circuit element disposed in said central cavity for processing said output signal from said force sensing element in each of said plurality of cavities; and

wiring electrically connecting each force sensing element in said plurality of cavities to said circuit element to transmit said output signal, said wiring disposed in a corresponding one of said plurality of wiring channels,

wherein said lower plate defines a plane parallel to the sagittal plane of the knee joint when the knee prosthesis is implanted therein,

wherein each of said four pairs of strain gages is aligned in a radial plane that is at about 45 degrees relative to said parallel plane, and

wherein none of said four pairs of radially aligned strain gages is aligned with said wiring channel communicating with said corresponding one of said plurality of cavities.

Claim 12 thus recites a telemetric knee prosthesis wherein none of the strain gages aligned at 45 degrees relative to a plane parallel to a sagittal plane is aligned with a wiring channel.

2. The Prior Art does Not Disclose Offset Strain Gauges

The Examiner did not specifically address the limitation of strain gages which are not aligned with a wiring channel much less strain gages aligned at 45 degrees relative to a plane parallel to a sagittal plane and which are not aligned with a wiring channel. Even if the strain gauges of Kovacevic are modified to be aligned at 45 degrees relative to a plane parallel to a sagittal plane, there is no motivation to further modify the alignment of the wiring channels of Kovacevic as claimed.

3. Conclusion

For the foregoing reason, it is respectfully submitted that the rejection of claim 12 as being obvious over Kovacevic has been successfully overcome, and the Applicants respectfully submit that claim 12 is allowable over the prior art.

Discussion Re: Patentability of Claim 13

Claim 13 depends from claim 12 and includes the limitations discussed above with respect to claim 12 and additional limitations. Accordingly, for at least the same reasons set forth above with respect to claim 12, claim 13 is patentable over the prior art.

III. Claims 14-18

New claims 14-18 have been added. These claims recite novel and non-obvious limitations. By way of example, the claims recite that a portion of the inner gauge is mounted on one side of the diaphragm directly opposite to where a portion of the corresponding one of the plurality of support posts contacts the other side of the

diaphragm. The prior art does not disclose such an arrangement. Accordingly, claims 14-18 are believed to be allowable over the prior art.

IV. Conclusion

Applicant respectfully requests entry of the amendments and favorable consideration of the application.

A prompt and favorable action on the merits is requested.

Respectfully Submitted,
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